

The Office Action indicated that the Japanese language document filed with the May 10, 2002, Information Disclosure Statement did not comply with 37 C.F.R. § 1.98(a)(3) because it did not include an explanation of the relevance of the document. The Applicants submit herewith a Supplemental Information Disclosure Statement including an English language abstract of Japanese publication no. 11-299901, and additional documents. The Applicants respectfully request consideration of the information in these documents.

The specification was objected to under 35 U.S.C. § 132 as introducing new matter into the disclosure. The Office Action stated that the Applicants did not show where the changes to the specification and claims had original support. The Office Action took the position that the deletion of “portion of” from page 4, line 3 appeared to change the original meaning of the specification. The Applicants respectfully submit that support for this amendment can be found on page 5, lines 4-11. Specifically, page 5, line 4 states that Fig. 1 illustrates a typical implantable prosthesis 10. Page 4, line 3, as amended, states that Fig. 1 is a simplified perspective view of a “typical intraluminal prosthesis,” which is implantable. As support for this amendment can be found in the specification as originally filed, the Applicants respectfully request withdrawal of the objection.

The Office Action also stated that the amendment on page 6, line 4 changed the original description of the device. The Applicants respectfully submit that support for this amendment can be found on page 6, lines 4-5 and 12, and page 6, lines 27-28. Specifically, the specification supports a plurality of arm elements as

recited on page 6, lines 4-5. Line 12 discloses that the arms can be helices, coiled, or braids which are known to be resiliently flexible. Further, page 6, lines 27-28 indicates that the arm elements are typically fabricated from a metallic material or an alloy, such as stainless steel, thereby indicating rigidity. Thus, the Applicants respectfully submit that support for this amendment can be found in the specification as originally filed. As such, the Applicants submit that no new matter has been added to the specification and respectfully request withdrawal of the objection.

The Office Action also took the position that the changed language in the paragraph on page 8, line 21 resulted in new matter. The Applicants respectfully submit that the changed language does not introduce new matter and the amendment is a rephrasing of an obvious typographical error. According to MPEP §2163.07:

“Mere rephrasing of a passage does not constitute new matter. Accordingly, a rewording of a passage where the same meaning remains intact is permissible. In re Anderson, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973).”

and

“An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction. In re Oda, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971).”

The Applicants respectfully submit that the originally disclosed phrase was obviously in non-idiomatic English and was rephrased in order to disclose the invention in idiomatic English. The specification, as originally filed, stated:

... the depth D₁ and breadth D₂ (*i.e.*, the volume) of each groove 32 in a row of grooves 32 on stent 20 can vary relative to each other groove in each other row of grooves 32.

The amended specification states:

... the depth D₁ and breadth D₂ (*i.e.*, the volume) of each groove 32 in a row of grooves 32 on stent 20 can vary relative to other grooves in other rows of grooves 32.

Thus, the amended paragraph is a grammatically correct version of the paragraph provided in the originally filed specification. Therefore, the Applicants respectfully submit that the amendment to the paragraph on page 8, line 21, does not result in new matter. Accordingly, the Applicants respectfully request withdrawal of the objection.

Claims 1-11 and 21-25 were rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification. Specifically, the Office Action took the position that the claim language “string-like” is not defined and lacks original support. The Applicants respectfully submit that the language “string-like” has support in the specification as originally filed. Page 11, line 13 of the specification states that “in one embodiment, monofilament 44 is processed to resemble a ‘string.’” Therefore, the monofilament can be described as “string-like,” since string-like is defined as resembling a string. See Webster’s Ninth New Collegiate Dictionary, page 692 (1987), the definition of “-like”. As such, the scope of the language “string-like” is originally defined and does not expand the original meaning of the specification.

Claims 1-11 and 21-25 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Office Action took the position that the phrase “string-like” renders the claims indefinite because the claims include non-disclosed elements. The Office Action indicated that “-like” was the same as the indefinite phrase “or the like” and references MPEP § 2173.05(d) as support for this proposition. The Applicants respectfully submit that MPEP § 2173.05(d) does not apply to the phrase “string-like,” because string-like is not the same as an element disclosed by “or the like”. MPEP § 2173.05(d) is directed to exemplary claim language which includes descriptions of examples or preferences recited in the claims. String-like does not encompass non-disclosed elements as string-like is not an example or a preference. String-like fully defines that the structure of the claimed filament resembles a string. Accordingly, the Applicants submit that Claim 1 is definite and respectfully request withdrawal of the rejection.

Claims 1-9, 11, 21, 22, 24, and 25 were rejected under 35 U.S.C. § 102(b) as being anticipated by Brown *et al.* (WO 98/23228), or alternatively, under 35 U.S.C. § 103(a) as being unpatentable over Brown *et al.* alone. The Applicants respectfully traverse the rejection and submit that claims 1-9, 11, 21, 22, 24, and 25 recite subject matter that is neither disclosed nor suggested by the cited prior art.

Claim 1 recites an implantable prosthesis, comprising a body structure having an outer surface for contacting a surface of a vascular lumen. A plurality of grooves is disposed on the outer surface of the body structure. Filament

portions having a string-like structure and containing a therapeutic substance are disposed in the plurality of grooves.

As a result of the claimed invention, a grooved stent can be deployed within the human vasculature with little or no significant loss of the therapeutic substance from the stent during delivery and expansion of the stent. The monofilament structure provides for increased control of the release rate of the therapeutic substance from the stent. The Applicants submit that the prior art of Brown fails to disclose or suggest the claimed invention, and therefore, fails to provide the critical and non-obvious advantages which are provided by the invention.

Brown discloses a directional drug delivery stent which includes an elongated or tubular member having a cavity containing a biologically active agent. The active agent diffuses from the reservoir cavity through directional delivery openings arranged on an outer surface of the elongated member.

With respect to Claim 1, the Applicants respectfully submit that Brown fails to disclose the claimed features of the invention. Claim 1 recites filament portions having a string-like structure and containing a therapeutic substance are disposed in the plurality of grooves. As set forth above, the feature of the filament portion having a string-like structure is definite. Accordingly, the Applicants respectfully submit that this feature must be given patentable weight. In contrast, Brown merely discloses an active agent 23, 25 in cavity 20 of delivery stent 70. As such, Brown fails to disclose or suggest the filament portions having a string-like structure. The active ingredients 23 and 25 are not disclosed as filament

portions having a string-like structure. The active ingredients in Brown are disclosed on page 7, lines 23-25. The active ingredients are disclosed as being anhydrous or aqueous solutions, among others. None of which indicate a string-like structure.

Anticipation requires that "the identical invention must be shown in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The test for anticipation requires that all of the claimed elements must be found in exactly the same situation and united in the same way to perform the same function in a single unit of the prior art. Studiengesellschaft Kohle, m.b.H. v. Dart Industries, Inc., 762 F.2d 724, 726, 220 USPQ 841, 842 (CAFC 1984). Anticipation cannot be predicated on teachings in a reference that are vague or based on conjecture. Datascope Corp. v. SMEC Inc., 594 F. Supp. 1036, 224 USPQ 694, 698 (D.N.J. 1984). Brown fails to show the identical invention as in as complete detail as is contained in the claim, in that Brown fails to disclose or suggest the claimed filament portion having a string-like structure. Nor is there any teaching or suggestion that the active agent is a filament portion having a string-like structure. As such, the Applicants respectfully submit that Brown cannot form the basis of a 35 U.S.C. § 102 rejection with respect to Claims 1-9, 11, 21, 22, 24, and 25. Accordingly, Brown does not anticipate Claims 1-9, 11, 21, 22, 24, and 25, nor are these claims obvious in view of Brown.

The Office Action also took the position that "if one does not consider the Active Agent with Carrier (23, 25) to be fibers, it is the Examiner's position that they are clearly suggestive thereof due to [the] cylindrical elongate structures. As discussed in the previous response to this Office Action dated May 10, 2002, the Applicants set forth that Brown lacks any suggestion or motivation for string-like filaments in the cavities and that the Office Action failed to meet the threshold requirement of *prima facie* obviousness by explaining why a cylindrical elongated structure would require string-like filaments. Under MPEP § 707.07(f), where the Applicant traverses any rejection, the Examiner should, if he or she repeats the rejection, take note of the Applicant's argument and answer the substance of it. In this case the Examiner did not explain why fibers are suggested due to cylindrical elongated structures. The Applicants submit that the cylindrical elongate structure in Brown has no bearing on the shape of the active agent. Therefore, it is the Applicants' position that the mere disclosure of a cylindrical elongated structure does not require or necessitate the use of filament portions having a string-like structure. Furthermore, the proposition that the use of cylindrical elongated structures requires string-like filaments is contrary to the description of the active agents given on page 7 of Brown. As discussed above, the active agents discussed in Brown include an anhydrous or aqueous solution, among others, with which to fill the cavities. None of the active agents is, or suggests a string-like filament.

Accordingly, the Applicants respectfully submit that the rejection of Claims 1-9, 11, 21, 22, 24, and 25 does not meet the requirement for proper rejection

under 35 U.S.C. § 103(a) as the reference does not teach or suggest all of the claimed limitations. Brown does not teach or suggest at least filament portions having a string-like structure and containing a therapeutic substance disposed in the plurality of grooves. Brown merely discloses an active ingredient, being an anhydrous or aqueous solution which fills the cavities. There is no teaching or suggestion that the active agents are filament portions having a string-like structure. In addition, there is no motivation in Brown or the prior art in general for requiring or suggesting filament portions have a string-like structure as an active agent merely because the stent in Brown is an elongated or tubular member. Further, there is no motivation in Brown or the prior art in general for modifying the active agent in Brown to assume the structural form as claimed in the present invention. As such, the Office Action has failed to establish a *prima facie* case of obviousness for purposes of a rejection of claims 1-9, 11, 21, 22, 24, and 25 under §103.

Claim 10 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Brown in view of Fischell et al. (U.S. Patent No. 5, 722,984, “Fischell”). The Office Action acknowledged that Brown fails to teach the use of a radioactive isotope as recited in Claim 10. Fischell was cited for curing this deficiency. Claim 10 depends from Claim 1.

Fischell discloses an antithrombogenic radioactive coating for an intravascular stent. Fischell does not disclose filament portions having a string-like structure. Therefore, the combination of Brown and Fischell fails to teach or

suggest each and every feature of the invention as recited in Claim 1. As such, the combination of Brown and Fischell fails to teach or suggest each and every feature of the invention as recited in dependent Claim 10.

Claim 23 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Brown. The Office Action acknowledged that Brown fails to disclose an adhesive bonding the string-like filament portion in the grooves.

As Brown fails to teach or suggest the invention as recited in Claim 1, from which Claim 23 depends, the reference fails to disclose the features of the invention as recited in Claim 23. Accordingly, the Office Action has not established a *prima facie* case of obviousness for purposes of a rejection under § 103.

Claims 1-11 and 21-25 are pending. Claims 2-11 and 21-25 depend from Claim 1. The Applicants respectfully submit that these depending claims are allowable for their dependency from allowable base Claim 1 as well as for the additional subject matter recited therein. As discussed above, the cited references fail to teach or suggest the claimed features of the invention. Accordingly, the Applicants respectfully request allowance of Claims 1-11 and 21-25, and the prompt issuance of a Notice of Allowability.

If for any reason, the Examiner determines that the Application is not now in condition for allowance, it is respectfully requested that the Examiner contact, by telephone, the Applicants' undersigned attorney at (415) 954-0323.

In the event this paper is not being timely filed, the Applicants respectfully petition for an appropriate extension of time. Any fees for such an extension, together with any additional fees, may be charged to Counsel's Deposit Account No. 07-1850.

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Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza, Suite 300
San Francisco, CA 94111
Telephone (415) 954-0200
Facsimile (415) 393-9887

Respectfully submitted,

47,271 Rhonda Bartongor /
Cameron K. Kerrigan
Attorney for Applicants
Reg. No. 44,826